मिसिल स.- 8(73)/2020/डी.पी/एनपीपीए-डीवी-II
F. No. 8(73)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 205/73/2020/F
Proceeding No : 205/73/2020/F

Minutes of the 205th (overall) and 73rd meeting of the Authority under DPCO, 2013 held on 25.02.2020 at 11:00 AM

The 205th meeting of the Authority (overall), which is the 73rd meeting under the DPCO, 2013, was held on the 25th of February, 2020 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following members of the NPPA were present:

(i) Ms. Ritu Dhillon, Member Secretary
(ii) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(iii) Ms. A. Srija, Economic Advisor, Deptt of Economic Affairs

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare was also present.

1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

(i) Shri Kalyan Nag, Advisor
(ii) Shri S. S. Ojha, Jt. Director (Pricing)
(iii) Shri Prasenjit Das, Asstt. Director (Pricing)
(iv) Shri Prakash Hemani, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 72nd meeting held on 20.01.2020.

1.1 Noted.

1.2 A note was made of the corrigendum to be issued for notification SO. No. 416(E) dated 28.01.2020 and the minutes wherein the strength of the formulation Dextromethorpran Hydrobromide+ Chlorpheniramine Maleate syrup for M/s Zydus Healthcare Ltd was mentioned as 5 mg instead of 4mg.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 72nd meeting dated 20.01.2020

2.1 Noted.

3. Agenda item no. 3 – Status of New Drug application

3.1 Noted.

4. Agenda item no. 4 – New Drug application Price fixation under para 5 of DPCO, 2013

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xiv) (total 14 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 12 (twelve) cases [except agenda no. 4(x) and 4(xi)] under para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Calcium Carbonate + Vitamin D3 + Methylcobalamine + L-Methylfolate Calcium + Pyridoxal-5 Phosphate Tablet	Each film coated Tablet contains: Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg, Vitamin D3 IP 2000IU, Methylcobalamine IP 1500mcg, L-Methylfolate Calcium 1mg, Pyridoxal-5 Phosphate 20mg	1 Tablet	M/s Eris Lifesciences Ltd.	17.48
4(ii)	Calcium + Vitamin D3 + Methylcobalamine + L-Methylfolate Calcium + Pyridoxal-5 Phosphate Tablet (CC 74 Xtra)	Each uncoated chewable tablet contains: Coral Calcium eq. to elemental Calcium 500mg, Vitamin D3 IP 2000IU, Mecobalamin (Methylcobalamin) IP 1500mcg, L-Methylfolate Calcium 1mg, Pyridoxal-5-phosphate 20mg	1 Tablet	M/s Windlas Biotech Private Limited /M/s Wockhardt Limited	17.48
4(iii)	Clopidogrel + Aspirin Tablet (Clopigal-AP-75)	Each film coated tablet contains: Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg, Aspirin IP 75mg	1 Tablet	M/s Rhydburg Pharmaceuticals Ltd. / M/s Galpha Laboratories Limited	3.68
4(iv)	Cilnidipine + Telmisartan + Chlorthalidone Tablet	Each Film Coated Tablet contains: Cilnidipine IP 10mg, Telmisartan IP 40mg, Chlorthalidone IP 6.25mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Limited / M/s Torrent Pharmaceuticals Limited	10.80
4(v)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	Each Film Coated Tablet contains: Thiocolchicoside IP 8mg, Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Lupin Limited	20.42
4(vi)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	Each Film Coated Tablet contains: Thiocolchicoside IP 4mg, Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Lupin Limited	13.28
4(vii)	Paracetamol +	Each 5 ml suspension contains:	1ML	M/s Hema Laboratories	0.80

	Chlorpheniramine + Phenylephrine Suspension	Paracetamol IP 125mg, Chlorpheniramine Maleate IP 1mg, Phenylephrine Hydrocloride IP 5mg		Pvt. Ltd. / M/s Zydus Healthcare Limited	
4(viii)	Paracetamol + Chlorpheniramine + Phenylephrine oral drops	Each ml oral drop contains: Paracetamol IP 125mg, Chlorpheniramine Maleate IP 1mg, Phenylephrine Hydrocloride IP 2.5mg	1 ML	M/s Hema Laboratories Pvt. Ltd. / M/s Zydus Healthcare Limited	3.12
4(ix)	Cefixime Trihydrate + Ofloxacin Tablet	Each film coated Tablet contains: Cefixime Trihydrate IP eq. to Anhydrous Cefixime 200mg, Ofloxacin IP 200mg.	1 Tablet	M/s Rivpra Formulations Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	11.19
4(x)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	Each Film Coated Tablet contains: Thiocolchicoside IP 4mg, Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s IPCA Laboratories Limited	Note 2
4(xi)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	Each Film Coated Tablet contains: Thiocolchicoside IP 8mg, Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s IPCA Laboratories Limited	Note 2
4(xii)	Efavirenz + Lamivudine + Tenofovir Disoproxil fumarate Tablet	Each film coated tablet contains: Efavirenz IP 400mg Lamivudine IP 300mg Tenofovir Disoproxil fumarate IP 300mg eq. to Tenofovir Disoproxil 245mg	1 Tablet	M/s Laurus Labs Ltd. / M/s Emcure Pharmaceuticals Ltd.	54.44

B. Retail price fixed under para 15 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xiii).	Ranitidine + Dicyclomine + Simethicone Tablet (Rantac Spas)	Each film coated tablet contains: Ranitidine Hydrochloride IP eq to Ranitidine 150mg, Dicyclomine Hydrochloride IP 10mg, Simethicone IP 20mg,	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Limited	4.86
4(xiv).	Paracetamol + Phenylephrine HCl + Chlorpheniramine Maleate + Sodium Citrate + Ammonium Chloride + Menthol Suspension (KOLQ Plus)	Each 5ml suspension contains: Paracetamol IP 250mg, Phenylephrine HCl IP 5mg, Chlorpheniramine Maleate IP 2mg Sodium Citrate IP 60mg, Ammonium Chloride IP 120mg, Menthol IP 1mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	1.08

Note 1: The retail prices are to be notified after 10 days from uploading of draft working sheet/ minutes of the 16th meeting of the Multidisciplinary Committee of Experts.

Note 2: Representation received from M/s IPCA Laboratories on draft working sheet which is under examination.

4.2 Agenda item no. 4(xv): The Authority deliberated upon the matter in details and approved the retail price of the formulations for the companies which have launched the without price approval as detailed below:

Sl.No.	Formulation	Approved retail price per tablet ex. GST (in Rs.)
1	Remogliflozin 100 mg + Metformin 500 mg tablet	11.54
2	Remogliflozin 100 mg + Metformin 1000 mg tablet	13.18
3	Dapagliflozin 5 mg+ Metformin 1000 mg tablet	39.98
4	Dapagliflozin 10 mg+ Metformin 1000 mg tablet	42.01
5	Dapagliflozin 10 mg+ Metformin 500 mg tablet	40.44
6	Empagliflozin 12.5 mg + Metformin 500 mg tablet	30.88
7	Empagliflozin 12.5 mg + Metformin 1000 mg tablet	32.45
	Empagliflozin 5 mg + Metformin 500 mg tablet	25.66

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted.

6. Agenda item no. 6 – Review application against ceiling price fixation of Ringer lactate Injection fixed vide S.O. 2401(E) dated 28.07.2017 filed by

(i) M/s Albert David Ltd
(ii) M/s Aculife healthcare Pvt. Ltd
(iii) M/s B. Braun Medical (india) Pvt. Ltd
(iv) M/s Fresenius Kabi India Pvt. Ltd
(v) M/s Ostuka Pharmaceuticals India Pvt. Ltd

6.1 The Authority deliberated upon the 5 review orders dated 21.03.2018 in respect of 5 companies related to ringer lactate injection.

6.2 The Authority was informed that as per decisions taken in its 69th meeting dated 08.08.2019, the matter had been referred to Department of Pharmaceuticals (DOP) vide communication dated 19.08.2019 wherein DOP was informed that a price increase due to

special packaging may distort market prices and accordingly sought clear directions in this regard.

6.3 DOP in its communication dated 16.12.2019 had replied to the above reference and requested to strictly implement review orders dated 21.03.2018.

6.4 Therefore, the matter was referred to the Multidisciplinary Committee of Experts in which 2 pharmacoeconomics experts were also associated on 02.12.2019.

6.5 The Authority was informed that the matter had been placed again in the in the 16th meeting of the Multidisciplinary Committee of Experts held on 13.02.2020 which noted that there is minor innovation in the packaging of the ringer lactate injection having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels and recommended an increase of 15% in ceiling price over and above the present applicable ceiling price.

6.6 The recommendation of the Committee were placed before the Authority and the Authority accepted the recommendation of the Committee and approved the ceiling price of ringer lactate injection with packages having special features as detailed below:

S. No.	Formulations	Unit	Ceiling Price excluding GST
1	Ringer lactate injection	100 ml pack (having special features)	Rs. 23.51
2	Ringer lactate injection	250 ml pack (having special features)	Rs. 40.08
3	Ringer lactate injection	500 ml pack (having special features)	Rs. 51.07
4	Ringer lactate injection	1000 ml pack (having special features)	Rs. 89.77

7. Agenda item no. 7 - Application of M/s Meril Life Sciences Pvt. Ltd. for Exemption under para 32(ii) of DPCO, 2013 for their product Sirolimus Eluting BioResorbable vascular scaffold system (MeRes100)

7.1 The Authority deliberated upon the matter in detail and noted the replies received from DCGI and DG-ICMR/ Standing National Committee on Medicines (SNCM) subsequent to NPPA's letter dated 21.10.2019 forwarding the safety concerns highlighted by All India Drug Action Network (AIDAN).

7.2 The Authority noted that subsequently, the DCGI had convened a meeting of experts wherein the experts had reviewed the data of the company as reported in the letter of DCGI dated 21.11.2019 as follows:

' On 17.09.2019, the firm had submitted 3 years clinical trial report of the clinical trial study of MeRes100-Sirolmus eluting Bioresorbable Vascular Scaffold system for the review of SEC (Cardiovascular & Renal).

The data submitted by the applicant was reviewed in consultation with SEC (Cardivascular & Renal) comprising of Cardiologists from VMMC & Safdarjung Hospital, New Delhi, Pharmacologist from VMMC & Safdarjung Hospital, New Delhi and Nephrologist from AIIMS, New Delhi in the meeting dated 07.11.2019 wherein, the firm presented three years follow up safety and efficacy data on MeRes 100- Sirolimus Eluting Bio-Resorbable Vascular Scaffold System in 108 patients. After detailed deliberation, the Committee felt that the data was satisfactory.'

7.3 The Authority further noted that SNCM vide its letter dated 04.12.2019 stated that

'*The Drug Controller General India (DCGI) has already submitted the detailed reply to you letter vide letter no: 12-01/19-DC(Pt-268) dated 21.11.2019, outlining the detailed procedure of approving the product which has undergone the defined process of consultation of experts. While considering any product the safety and efficacy is considered by experts and the committees. The letter is DCG(I) is attached for ready reference.*

We would further recommend DCG(I) to ensure close safety monitoring of the above mentioned product.'

Accordingly, the Authority noted that the concern regarding safety had been duly addressed.

7.4 The Authority in its meeting of 09.12.2019 and 20.01.2020 had sought clarification from the Office of the Controller General of Patents, Designs & Trademarks on the nomenclature of the products and asked the Office of the Controller General of Patents, Designs & Trademarks

"to clarify whether the words "bioabsorbable" and "bioresorbable" are used interchangeably and are having the same meaning.

It may also be clarified as to whether the patent no. 296768 which mentions 'annealing process for a bioabsorable stent' can be read as 'annealing process for a bioresorable stent'."

7.5 The Office of the Controller General of Patents, Designs & Trademarks vide its reply dated 10.02.2020 has clarified that **" *... the title of invention as "Annealing process for a bioabsorbable stent", can be read as "Annealing process for a bioresorbable stent", as the terms such as Bioabsorbable, bioresorbable and biodegradable are used interchangeably in the patent specification.*"**

7.6 The Authority thus noted the clarification provided by the Office of the Controller General of Patents, Designs & Trademarks thereby establishing consonance in the certificate of the Patent Office and the name of the product as mentioned in the new drug approval by DCGI and the application of the company.

7.7 The Authority deliberated upon the matter at length and observed the following:

a) Establishing significant therapeutic advantage and increased efficacy is not a pre-requisite for obtaining exemption under para 32(ii) of DPCO 2013.

b) The safety concerns of the product in question are not required to be examined by the Authority in order to consider a case for grant of exemption under para 32(ii) of DPCO 2013. The 'new drug" approval certificate of the DCGI and the grant of Indian Patent being the two essential conditions. However, issues related to safety concern were referred by the Authority to SNCM and DCGI to seek assurance in public interest.

c) The Multidisciplinary Committee of Experts in its meeting dated 07.02.2019 had found the case fit for grant of exemption under para 32(ii) of DPCO 2013 and observed as under:

The committee deliberated the issue in details and observed that the company has submitted the following documents:
(i). Copy of patent certificate no. 296768 dated 14.05.2018 issued to M/s Meril Life Sciences Pvt Ltd by The Patent Office, Government of India for "annealing process for bioabsorbable stent".
(ii). DCGI vide its letter no. 4-MD/CT-108/2013-DC dated 19.04.2017 conveyed approval stating that "Sirolimus Eluting BioResorbable vascular scaffold system (MeRes 100)" falls under new drugs as per Rule 122E of Drugs and Cosmetic Rules, 1945.

The committee found that the submission of above documents meets the requirements of para 32(ii) of DPCO, 2013.

d) Coronary Stents namely (i) Bare Metal Stents and (ii) Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents are scheduled drugs which have been brought under price ceiling vide NPPA's order dated 13.02.2017 and subsequent orders dated 01.04.2017, 12.02.2018, 02.04.2018 and 29.03.2019. With a grant of exemption as per para 32(ii) of DPCO 2013, the provisions of DPCO 2013 would cease to apply on the said product.

7.9 After much deliberation, the Authority decided that exemption may be granted to M/s Meril Life Sciences Pvt. Ltd under para 32(ii) of DPCO, 2013 for their coronary stent 'MeRes 100- Sirolimus Eluting Bio-Resorbable Vascular Scaffold System' as per the recommendation made by the Multidisciplinary Committee of Experts.

7.10 The Authority also directed DCGI to ensure close safety monitoring of the coronary stent MeRes 100- Sirolimus Eluting Bio-Resorbable Vascular Scaffold System in public interest.

8. Agenda item no. 8 - Recommendation of Standing National Committee of Medicines (SNCM) against ceiling price fixation of Paclitaxel Injection based on representation made by M/s Fresenius Kabi India Pvt. Ltd – regarding nano based formulation.

8.1 The Authority deliberated upon the matter in detail and noted that NPPA had fixed the ceiling price of Paclitaxel injection 100mg/16.7 ml and Paclitaxel Injection 30mg/ 5ml, being scheduled formulations, by including the product "Nanoxel" of M/s Fresenius Kabi India Pvt. Ltd which is a nano based formulation.

8.2 The company had represented that its formulation was not a regular formulation and therefore should be excluded from the calculation,

8.3 The Authority further noted the review order no. 31015/33/2016-PI.I dated 19.09.2016 issued by Department of Pharmaceuticals (DOP) directing NPPA to revise the prices within one month of this order of all the three cases of the petitioner company in the light of para 11(3) of DPCO, 2013 and strictly in accordance with para 4 of DPCO 2013. Accordingly, the matter had

been referred to Standing national Committee on Medicines (SNCM) which vide its letter dated 10.07.2019 stated that it "…*has not found sufficient evidence to catogorise the nano formulations of paclitaxel as 'essential'. However, nano formulation is an innovative product."*

8.4 Further, it was noted that, advise was sought by the Authority on the categorization of the product and Department of Pharmaceuticals vide its letter dated 12.02.2020 stated that "…*NPPA is requested to arrive at a final decision keeping in view the recommendation of SNCM, clarification of DCGI and the examination of the relevant documents of M/s Fresenius Kabi India Pvt. Ltd as per the claim cited above."*

8.5 After in depth analysis, the Authority decided that based on the clarification of SNCM, the product 'Nanoxel-the nano based formulation of Paclitaxel' is not a scheduled formulation. However, since it is a variant of the scheduled formulation "paclitaxel", the nano based formulation of paclitaxel is to be treated as new drug under para 2(u) of DPCO 2013. The Authority also directed to re-fix the ceiling price of Paclitaxel injection 100mg/16.7 ml and Paclitaxel Injection 30mg/ 5ml by excluding the product "Nanoxel" of M/s Fresenius Kabi Pvt. Ltd.

8.5 The Authority further decided that the provisions of DPCO 2013 relating to "new drugs" under para 2(u) is not applicable to "nanoxel" product of M/s Fresenius Kabi Pvt. Ltd since it was launched prior to enactment of DPCO 2013 and DPCO 2013 requires only the existing manufacturer to seek prior price approval for launch of new drugs after enactment of DPCO 2013, under para 15 of DPCO 2013

9. Agenda item no. 9 - Fixation of Ceiling Price of Calcium Carbonate 500mg Tablets under para 19 of DPCO, 2013 based on Institutional Data received from Hospitals

9.1 The Authority noted that to fix the ceiling price of the scheduled formulations based on the communication of Department of Pharmaceuticals (DOP) dated 05.02.2019, in cases where no market data is available, NPPA had taken extra efforts to collect the institutional data. Letters were issued to Director General Health Services (DGHS), Central drug procurement agencies; state drug procurement agencies, state drug controller (SDC), Central/State Government Hospitals and private Hospitals, etc in order to obtain the data from the required Institutions. The services of Standing National Committee on Medicines (SNCM) were also obtained in collecting the requisite data. Despite such elaborate efforts, data could not be collected in respect of some of the scheduled formulations as stipulated.

However, NPPA had, on own initiative, put the data in public domain to invite concerns, if any.

9.2 The Authority further noted the representations received from representation from Confederation of Indian Industry (CII), New Delhi and Indian Pharmaceutical Alliance (IPA), Mumbai for providing 24% margin on the draft calculation uploaded in NPPA's website based on its earlier decision in the meeting dated 20.01.2020. In this connection, the Authority took cognizance of the fact that NPPA had earlier fixed the ceiling price of certain scheduled formulations based on institutional data by giving nil margin for which representations were received from the state agencies of Karnataka, West Bengal, Rajasthan, Assam and Bihar. The agencies stated that they were not able to procure citing the inability to supply within the ceiling price notified by NPPA. The Hon'ble High Court of Madhya Pradesh had also passed an order in this regard. Accordingly, the Authority agreed to allow 24% margin on average procurement price at institutional level.

9.3 The Authority deliberated upon the matter at length and opined that delay in giving ceiling price of these scheduled formulations would delay the benefit of ceiling price being passed on to the consumers.

9.4 Accordingly, the Authority approved the ceiling price of 5 scheduled formulations based on the institutional data available in public interest as detailed below:

S. No.	Formulation	Approved Ceiling Price (ex GST)
1.	Calcium Carbonate 500mg Tablet	Rs. 1.69 per Tablet
2.	Ferrous Salt 100mg + Folic Acid 500mcg tablet	Rs. 0.23 per Tablet
3.	All-trans Retinoic Acid 10mg capsule	Rs. 80.05 per capsule
4.	Daunorubicin 5mg/ml injection (20mg pack)	Rs. 237.98 per pack
5.	Ethyl Alcohol (Denatured) 70% solution	Rs. 0.41 per ml

9.5 The Authority further directed that action may be taken against Max hospital, Gurugram for sale of Calcium Carbonate 500 mg tablet for violations of the provisions of DPCO 2013.

10. Agenda item no. 10 - Issues relating to launch of drugs under para 32 of DPCO 2013

10.1 The Authority deliberated upon the matter in detail and decided that action may be taken for recovery of the overcharged amount based on the provisions of DPCO 2013 read with internal guidelines against the existing manufacturers which have launched the drugs without price approval.

10.2 The Authority further decided that in respect of the companies who are not the existing manufacturers, action be taken for violations of para 20 of DPCO 2013.

11. Agenda item no. 11 - Intimation of Minutes of 16th meeting of Multidisciplinary Committee of Experts held on 13.02.2020.

11.1 Noted.

12. Agenda item no. 12 – Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

Record note of discussion.

13. Agenda item no. 13 - Monitoring the prices and availability of APIs/ Intermediates/ KSMs which are primarily imported from China to address the drug security in the country in the context of Novel Coronavirus (COVID-19) outbreak in China

13.1 Noted.

13.2 The Authority stressed that situation arising from Corona virus outbreak was a wakeup call regarding drug security in the country hence there is a need to build capacity for indigenous production of bulk drugs.

14. Agenda item no. 14 – Price fixation of anti-cancer drugs under Trade Margin Rationalisation (TMR) approach

14.1 The Authority deliberated upon the matter in detail and decided that in continuation of the notification S.O. 1041(E) dated 27.02.2019, the price as revised by the manufacturers subsequent to the notification be continued to be monitored as per the provision of paragraph 20(1) of DPCO, 2013.

The meeting ended with a vote of thanks to the Chair.

Sd/-
(Ritu Dhillon)
Member Secretary